UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,793	03/26/2004	Zhijian J. Chen	MPI96-031CP1DV1CPACN2M	1019

30405 7590 10/12/2007

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	-

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,793	CHEN, ZHIJIAN J.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8 and 10-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed on 08/13/2007, are acknowledged.

Claims 7 – 8 and 10 – 19 are pending.

The rejections of record can be found in the previous Office Action, mailed on 05/12/2006.

The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments.

It is noted that New Grounds of Rejection are set forth herein.

2. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7 – 8 and 10 – 19 stand rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of an antibody or an antigen-binding fragment thereof which binds specifically to a generically recited "a kinase or a subunit thereof," wherein the kinase is defined solely by its ability to phosphorylate IκBα at the specified residues and by approximate molecular weight.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the disclosed and claimed characteristics of substrate specificity to serine residues 32 and 36, and the approximate molecular weight of the complex, distinguish the recited kinase from those known in the art.

This is not found sufficiently persuasive, because the recited genus of kinases is defined by a single functional characteristic (i.e. substrate specificity) and a single physical property (i.e. approximate molecular weight). There appears to be no known or disclosed correlation between the recited function and the recited physical property, to adequately describe the recited genus. The references cited in the previous office action serve to exemplify the structural and functional variability of kinases, even if the references do not specifically teach the recited combination of functional and physical properties. Furthermore, the absence of specific disclosure in the references of the ability of other kinases known in the art to phosphorylate serines 32 and 36 of IκB does not imply the absence of such ability.

Applicant further argues that the specification discloses a representative number of species within the recited genus, namely MEKK1-dependent and ubiquitin-dependent kinases of approximately 700 kDa.

This is not found sufficiently persuasive, because the two disclosed species do not appear to shear any known or disclosed structural features that would allow the skilled artisan to envision all the contemplated structural possibilities encompassed by the recited genus. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Therefore, the rejection of record is maintained essentially for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

New Grounds of Rejection

4. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 7 – 8 and 10 – 19 are rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by McGuire et al. (US Patent No. 5,447,843; see entire document) as evidenced by Scheidereit (Oncogene, 2006, 25: 6685 – 6705; see entire document).

McGuire et al. teach a monoclonal antibody which binds specifically to hsp90 (e.g. column 11 lines 6 – 12 and column 19 lines 47 – 57).

Scheidereit provides evidence that hsp90 is a subunit of an IKK complex, a 700 – 900 kDa kinase complex which phosphorylates IκBα at serine residues 32 and 36 (see entire document, in particular, e.g. page 6686 second column, Table 1 at page 6687, and page 6689 second column, first full paragraph).

Therefore, the antibody taught by McGuire et al. specifically binds to a subunit of a kinase which phosphorylates IκBα at serine residues 32 and 36, the kinase being a complex of approximately 700 kDa molecular weight.

McGuire et al. further teach and claim methods of detecting hsp90 (and hence of complexes comprising hsp90) in a sample, and kits comprising containers comprising anti-hsp90 antibodies and a label or a detection reagent (e.g. claims 1, 11, and 15 – 23). McGuire et al. also teach an anti-hsp90 antibody immobilized on solid support, and detectably labeled with a radioisotope (e.g. Example 1 at column 19, and Figure 1). Claim 12 is included in the rejection, because a teaching of a monoclonal antibody inherently includes a teaching of the corresponding hybridoma. Claim 10 is included in the rejection, because the claim is directed to an "antibody or an antigen-binding fragment," and as such, is not limited to a fragment, i.e. is anticipated by the teaching of an antibody. Furthermore, one of skill in the art would immediately envisage an antigen-binding fragment of an anti-hsp90 antibody in view of the teachings of such antibody.

Therefore, the reference teachings anticipate the instant claimed invention.

6. Conclusion: no claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilia Ouspensk.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

October 9, 2007